K 100853

510(k) SUMMARY

MAR 10 2010

Submitter:	Mattioli Engineering Corporation
Contact:	Gian Franco Bernabei
Date Summary Prepared:	december 11, 2009
Device Trade Name:	Mattioli Pulse Two/Three Plus Family
Common Name:	IPL system generator
Classification Name:	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect ONF 21 CFR 878.4810
Equivalent Device:	Advanced Technology Laser, Co., Ltd.: Angelite Family of Intense Pulsed Light Systems

Device Description:

The MATTIOLI PULSE TWO/THREE Plus Family is an Intense Pulse Light (IPL) generator device producing on the skin different effects depending on the applicator used by the operator:

SR Applicator: its purpose is to stimulate the regenerative process of the skin. It uses the principle of the selective absorption of the different light wavelengths , without damaging the skin structure.

HR Applicator: its purpose is to destroy thermally the hair bulb, due to the absorption of a selected range of radiated wavelength. The selective absorption of different wavelengths is either used by HR to obtain the desired effect without damaging the surrounding skin structures .

VR Applicator : Its purpose is to treat benign pigmented (epidermal and cutaneous) lesions including warts scars abnd striae . It is also intended for treatment of benign (cutaneous) vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangectasias, rosacea,

melasmna, angiomas and spider angiomas, polkiloderma of civatte; leg veis, facial veins and venous malformations.

The two systems differ substantially only by the case: it is "desktop" style for MATTIOLI PULSE TWO PLUS device and a standard case, with wheels to allow easy movement on the floor, for PULSE THREE PLUS device.

Both equipments consist of a console, containing the electronic supply system for capacitor bank charge , the computerized control system (CCS) , and one or two hand pieces in which are contained the light generators devices (flash lamp) and the necessary filtered light guide for the selection of the wavelengths range.

The computerized control system (CCS) monitors and controls either the equipment and interfaces with the operator, through an 8.2" colour back lighted LCD screen display and a touch screen panel, displaying all the selected parameters and indications on the status of the machine. The selection of each command and parameter simply occurs by touching the LCD screen.

Each applicator is composed basically by the flash-lamp, a water cooled reflector, a filtered light guide, a light guide cooler, a flash-counter and the pushbutton for the activation of flash emission.

Intended Use:

The MATTIOLI PULSE TWO/THREE PLUS is an Intense Pulse Light (IPL) device family indicated for use in aesthetic and cosmetic applications (based on selective photothermolysis, in the treatment of acne, various benign pigmented lesions and hair removal and that produce different effects depending on the applicator that is used:

HR APPLICATORS:

Intense Pulse Light Energy Wavelengths from 650 (HN type) or 710 (HF type) - 960 nm are indicated for the treatment of unwanted hair (i.e., hair removal).

SR APPLICATOR:

Intense Pulse Light Energy Wavelengths from 560 - 960 nm are indicated for skin resurfacing procedure , for the treatment of inflammatory acne and decrease the appearance of dark spots.

VR APPLICATOR

Intense Pulse Light Energy Wavelengths from 510 - 960 nm are indicated for the treatment of benign pigmented (epidermal and coetaneous) lesions including warts, scars and striae. For the treatment of benign (cutaneous) vascular lesions including port wine 'stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasmna, angiomas and spider anglormas, polkiloderma of civatte; leg veins, facial veins and venous malformations.

Rationale for Substancial Equivalence:

The product specification, functionality, indication for use, and treatment parameters of the Mattioli Pulse Two/Three Plus Family are the same or very similar to the legally marketed Angelite Family of Intense Pulsed Light Systems.

Both systems have the same indication for use.

Both systems uses a flash lamp, which emitted light is delivered to the patient via a glass light guide.

The Mattioli Pulse Two/Three Plus Family output characteristics (including pulse duration and fluence) are identical, or very similar, to those of the predicate device.

Both systems are microprocessor controlled devices.

Both systems utilize an internal closed loop water-air heath exchanger circuit for optimal thermal control of system temperature.

The risks and benefits for the Mattioli Pulse Two/Three Plus Family are comparable to those for the predicate device. Therefore, the introduction of this IPL device should not raise new questions of Safety and Effectiveness .

Non-Clinical Performance Data: None

Clinical Performance Data: None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mattioli Engineering Corporation
% Mr. Gian Franco Bernabei
8300 Greensboro Drive, Suite 800
McLean, Virginia 22102

MAR 10 2010

Re: K100053
Trade/Device Name: Mattioli Pulse Two/Three Plus Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: February 25, 2010
Received: March 01, 2010

Dear Mr. Bernabei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

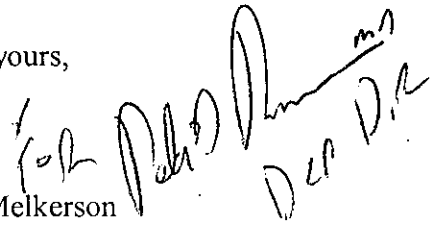
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K100053

Device Name: Mattioli Pulse TWO/THREE Plus Family

Indications for Use:

The MATTIOLI PULSE TWO/THREE PLUS is an Intense Pulse Light (IPL) device family indicated for use in aesthetic applications (based on selective photothermolysis) , in the treatment of various benign pigmented lesions and hair removal and that produce different effects depending on the applicator that is used:

SA APPLICATOR:
Model SN: Wavelengths from 560 - 1200 nm are indicated for treatment of benign pigmente (epidermal and coutaneous) lesions, including hyperpigmentation, warts, lentigines, nevi, melasma, and cafe-au-lait.

VA APPLICATOR
Model VN: Wavelengths from 510 - 1200 nm are indicated for the treatment of benign vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider anglormas, polkiloderma of civatte; leg veins, facial veins and venous malformations.

HR APPLICATORS indicated for the treatment of unwanted hair (i.e. hair removal).
Model HN: Wavelengths from 650-1200 nm for skin types I-IV;
Model HF: Wavelengths from 710 - 1200 nm for skin type V

The equipment should only be used under medical supervision.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices Page __ of ___

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